K013695

JAN 0 8 2002

11. SMDA Summary of Safety and Effectiveness - "510(k) Summary"

A. **Submittor Information**

Sponsor:
Microline, Inc.
C/o Interactive Consulting
70 Walnut Street
Wellesley, MA 02481
Tel: 781 239-8108
Fax: 781 863-6488
Contact Person: Dr. Jean-Luc Boulnois
Date Prepared: November 5, 2001

Manufacturer
Microline, Inc.
800-257-X Cummings Center
Suite 157-X
Beverly, MA 01915
Tel: 978 922-9810
Fax: 978 922-9209

B. **Device Identification**

Common/Usual Name: Laparoscopic Clip Cartridge with Implantable Titanium Clips Model M/L-10

Classified Name: Implantable Clip (74FZP), 21 CFR 878.4300, Class II

C. **Identification of Predicate Device(s):** Applied Medical and Ethicon Endosurgery

D. **Device Description**

The Microline Reusable Laparoscopic Clip Applier with Implantable Titanium Surgical Clips is a reusable instrument designed for use with a disposable clip cartridge that is advanced inside the clip applier shaft. The rotatable clip applier shaft is sized to fit through a 10mm trocar. The Microline Reusable Laparoscopic Clip Applier is sold with a pre-loaded clip cartridge which contains 19 rectangular implantable titanium single-use surgical clips (width 5.4mm) that can be applied one at a time after firing. Cartridge loading is performed through a slot located in the rear of the instrument, in line with the instrument's shaft. Cartridge loading and unloading can be performed in-vivo without removing the Clip Applier from the trocar.

E. **Intended Use**

The Microline Reusable Laparoscopic Clip Applier with Implantable Titanium Surgical Clips is intended for use to occlude vessels, ducts, tracts and other tubular structures during laparoscopic and general surgical procedures.

F. **Technolological Characteristics:**

The Microline Reusable Laparoscopic Clip Applier with Implantable Titanium Surgical Clips shares the same technological characteristics as the predicate devices in that they are comprised of similar design, materials, and intended use.

G. **Conclusion of Substantial Equivalence**

The Microline Reusable Laparoscopic Clip Applier with Implantable Titanium Surgical Clips has the same intended use and the same basic technology as the predicates identified in the Premarket Notification Submission. The Microline Reusable Laparoscopic Clip Applier with Implantable Titanium Surgical Clips contain in some combination similar features, materials, and design as the predicates and does not pose any new questions concerning safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 0 8 2002

Microline, Inc.
c/o Ms. Jacqueline E. Masse
Senior Consultant
Interactive Consulting
70 Walnut Street
Wellesley, Massachusetts 02481

Re: K013695
Trade/Device Name: Microline Reusable Laparoscopic Clip Applier
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable Clip
Regulatory Class: Class II
Product Code: FZP
Dated: November 05, 2001
Received: November 07, 2001

Dear Ms. Masse:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K013695

Device Name: Microline Reusable Laparoscopic Clip Applier with Single Use Titanium Clips Model M/L-10

Indications For Use:

To occlude and ligate vessels, ducts, tracts, and other tubular structures during Laparoscopic and general surgical procedures

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

NKO for c mw

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K013695

Prescription Use X OR Over-The-Counter Use_____
(Per 21 GFR 801.109)

(Optional Format 1-2-96)